

**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

In re Application of:
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Abbot F. Clark
Rajni Jani
Stella M. Robertson

Group Art Unit: 1617

Examiner: S. Hui

Atty. Dkt. No.: 2471 US

Serial No.: 10/772,963 (Conf. #5299)

Filed: February 5, 2004

For: FORMULATIONS OF
GLUCOCORTICOIDS TO TREAT
PATHOLOGIC OCULAR ANGIOGENESIS

**AMENDMENT and RESPONSE TO OFFICE
ACTION DATED FEBRUARY 14, 2006**

Mail Stop Amendment
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amendment is filed in response to the Final Official Action mailed February 14, 2006, for which the three-month date for response is May 15, 2006, by virtue of May 14, 2006, being a Sunday.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Alcon, Inc. Deposit Account No. 501051.

Reconsideration of the application is respectfully requested.

There are no **Amendments to the Specification** in this paper.

There are no **Amendments to the Claims** in this paper.

There are no **Amendments to the Drawings** in this paper.

Remarks/Arguments begin on page 5 of this paper.

I. REMARKS:

A. Status of the Claims

Claims 1-2 were originally filed with the case. Claims 3-18 were added in a Response to Office Action filed on March 9, 2005. Claims 1, 3, 4, 6, 8, 10, and 16 were and claim 2 was canceled in a Response to Office Action dated November 15, 2005. No claims are amended, added, or canceled herein. Thus, claims 1, and 3-18 are currently pending.

B. The Claims are Patentable Over U.S. Patent 5,516,522 and Clark

The Action rejects claims 1-5 and 8-18 as being obvious over U.S. Patent No. 5,516,522 (Peyman) and Clark. Peyman is said to teach prednisolone, prednisolone acetate, triamcinolone, fluoromethalone, and fluoromethalone acetate as useful in treating proliferative vitreoretinopathy and that the ocular formulation may be an intraocular implant. Clark is said to teach anecortave acetate as useful in treating ocular neovascularization. The Action acknowledges that the references taken together do not expressly teach the incorporation of both steroids and anecortave acetate together in a method of treating angiogenesis disorders, nor do they teach the claimed dosages. Nevertheless, the Action asserts that it would have been obvious to combine the references because each element was known separately. Applicants respectfully traverse.

As pointed out in the Response filed November 15, 2005, Peyman appears to describe a biodegradable drug delivery device designed to solve the problem of prolonged drug release into the vitreous of the eye that does not have to be removed after delivery of all of the drug in the device. While Peyman '522 patent mentions the potential use of steroids in the device described therein, it does not provide any teaching or suggestion of dosage amounts of particular steroids for the treatment of pathologic ocular angiogenesis. Nor does

Peyman contain any mention of the use of anecortave acetate with the steroids for the treatment of pathologic ocular angiogenesis.

The issue is whether the subject matter claimed would have been obvious, at the time of the present invention, to one of ordinary skill in the art. The question is not whether using two different compounds to treat pathologic ocular angiogenesis is obvious, but rather, whether using two different compounds in the same composition is obvious. It is clear that the proper approach to the obviousness issue must start with the claimed invention as a whole. 35 U.S.C. § 103; *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724 (Fed. Cir. 1990). While it may be true that the present invention consists of a combination of old elements so arranged as to perform certain related functions, that is immaterial to the issue. It is well settled that “what must be found obvious to defeat the patent is the claimed combination.” *Id.* (quoting *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448, 223 U.S.P.Q. 603, 609-10 (Fed. Cir. 1984) (emphasis added)).

The Action has failed to provide evidence of motivation to the skilled artisan to combine the teachings of the cited references to arrive at a method of treating pathologic ocular angiogenesis by administering a single composition containing the two compounds. Rather, the Action has simply restated the position that it would have been obvious because the two compounds have been used separately. The Federal Circuit has clearly established that this is not the proper inquiry for obviousness (*see Gillette and Kimberly Clark supra*).

In light of the foregoing arguments, Applicants respectfully request that the obviousness rejection based upon Peyman and Clark be withdrawn.

C. The Claims are Patentable Over WO95/03807 and Clark

The Action next rejects claims 1-2, 4-5 and 16-18 as being unpatentable over WO 95/03807 ('807) and Clark. Reference '807 is said to teach a method of treating neovascular macular degeneration by administration of triamcinolone and that the drug may be administered by intravitreal injection. Clark is said to teach a method of treating ocular neovascularization disorders using anecortave acetate. The Action acknowledges that the references taken together do not teach the incorporation of both the triamcinolone and anecortave acetate together in a method of treating angiogenesis disorders. The Action asserts that it would have been obvious to incorporate triamcinolone and anecortave acetate together in a method of treating angiogenesis disorder. Applicants respectfully traverse.

As with the rejection discussed above, the rejection of the claims as being obvious over the '807 reference and Clark amounts to a statement that it would have been obvious to combine the two compounds for the treatment of pathologic ocular angiogenesis because each compound was known separately. Applicants arguments provided above with respect to the obviousness rejection based upon Peyman and Clark apply equally with respect to the rejection based on the '807 reference and Clark. Neither reference mentions the claimed combination for the treatment of pathologic ocular angiogenesis, as the Action admits. According to the established caselaw, a clear explanation of the motivation for the combination is required in order to establish obviousness. That explanation has not been provided.

In light of the foregoing arguments, Applicants respectfully request that the obviousness rejection based on the '807 reference and Clark be withdrawn.

D. Conclusion

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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